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CORPORATE OFFICE

May 24, 2007

VIA FACSIMILE

David A. Neumann, PhD  
Health Policy Analyst, Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215.

Re: COMAR 10.24.05, Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery

Dear Dr. Neumann:

On behalf of the University of Maryland Medical Center (UMMC), Baltimore Washington Medical Center (BWMC) and Shore Health System (SHS), the University of Maryland Medical System (UMMS) offers the following comments with regard to the proposed draft regulations in the above matter.

We would first like to extend our appreciation to the Commission for convening the research advisory council which carefully evaluated Dr. Aversano's study and for proposing regulations to allow selected qualified hospitals to participate in this very important research. While it is clearly understood that many of the guidelines for participation are specifically defined in the research study itself, we also request that several of the proposed regulations should be clarified or modified.

#### **10.24.05.02. Purpose**

It would be helpful to have clarification of .02.A. which defines this as a "one-time process". If a qualified hospital applies for a waiver and is not approved, would there be an opportunity to reapply under certain circumstances (e.g. enrollment at other participating hospitals is slower than expected)? Does "one-time" refer to the fact that there will be only one opportunity throughout the term of the study to submit an application for a waiver? If an approved hospital should lose its waiver, would another qualified hospital be permitted to apply for the waiver? Please clarify.

.02.C. The waiver process should allow any hospital that can demonstrate an ability to meet the final review criteria to participate. The proposed limit on the number of hospitals that can receive a waiver (6) seems fairly arbitrary. The research study clearly sets specific patient enrollment targets. It is our opinion that enrollment of patients could be done more efficiently, and to reflect a greater level of diversity, if all qualified hospitals are allowed to participate.

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#### **UNIVERSITY OF MARYLAND MEDICAL SYSTEM**

University of Maryland Medical Center

University Hospital • R Adams Cowley Shock Trauma Center • University of Maryland Marlene and Stewart Greenebaum Cancer Center

University of Maryland Hospital For Children • University Specialty Hospital

Kernan Orthopaedics and Rehabilitation • Maryland General Hospital • Baltimore Washington Medical Center • Mt. Washington Pediatric Hospital

Shore Health System-Memorial Hospital at Easton • Dorchester General Hospital

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#### 10.24.05.03B – Eligibility to File

The proposed regulations only allow for a hospital to apply for a waiver if it "has a 2-year waiver to perform primary PCI". It should be noted that, currently, no hospital which is performing primary PCI under this definition has been granted a 2 year waiver. Given that the reapplication process for existing 1-year waivers is currently in process, we would propose that the eligibility criteria allow hospitals with any waiver for primary PCI to apply. The specific exception for Eastern Shore and Western Maryland hospitals should apply to all Maryland hospitals. Hospitals with a waiver for primary PCI have demonstrated that they meet the stringent criteria established for participation. It is our assertion that those hospitals and their patients would only benefit from the ability to increase their eligible patient population for PCI – primary or non-primary.

The attempt to balance geographic access during the waiver period with the ultimate research goal of gathering sufficient data to draw conclusions about the future of non-primary PCI should be re-assessed.

#### 10.24.05.04.A(3) Review of Applications

In addition to the factors listed that the Commission may consider, UMMS requests that the Commission also consider the total volume of cardiac patients at each hospital and in each hospital's geographic service area. The overall volume of cardiac patients would clearly impact the potential enrollment of patients into this research study at a given hospital. Additionally, we would propose that the Commission provide potential applicants with more detail as to the weight given to the individual factors listed in this section. We would also ask for clarification of how the three major performance indicators for the current primary PCI waiver (door-to-balloon time; volume and success rates) will be evaluated.

Thank you for the opportunity to share our thoughts on this important issue.

Sincerely,



Edmond F. Notebaert  
President and Chief Executive Officer  
University of Maryland Medical System